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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,663	11/29/2001	Lorraine Faxon Meisner	121753-1004	5796

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,663	MEISNER, LORRAINE FAXON	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8 and 10-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/21/2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17, 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the disclosed process of pretreating the ascorbic acid and ascorbic acid which has been pretreated according to said process in the disclosed amounts and temperatures, does not reasonably provide enablement for other processes of pretreating the ascorbic acid or ascorbic acid pretreated by other processes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The invention is directed to pretreatment of ascorbic acid. The prior art does not appear to disclose pretreatment of ascorbic acid as disclosed in the Specification as such predictability in the art appears to be low. The Specification does not appear to disclose any other method of pretreating ascorbic acid. The claims are broad in that they indicated "pretreatment" but do not define the same in the claim. As such, one of ordinary skill in the art would be required to due undue experimentation in order to determine what other methods would be suitable for pretreating the ascorbic acid which results in the same or similar characteristics of the disclosed invention.

Claims 17,18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are the process steps by which the ascorbic acid is pretreated. The Specification explicitly discloses that between 10% and 50% of the ascorbic acid is pretreated and/or stabilized by heating a specified concentration of ascorbic acid at a specified temperature range and pH of at least 3.5 (Pg. 8, lines 3-10, Pg. 9, lines 7-15, pg. 16, lines 12-26). The Specification does not appear to disclose or suggest alternative methods of pretreating the ascorbic acid, as such, the process appears to be critical to the invention and should be included in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,3-8, 10-16, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594) and Herstein (US Pat. 5,902,591).

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which is applied once or twice daily (Column 2, lines 38-53, Column 4, lines 34-45, Claims 1, 2).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucoseamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught that zinc binds collagen fibers and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Herstein teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 2, lines 40-47, Column 10, lines 6-17).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, aminosugar, water and pH of 3.5 to 4.1. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and glucosamine, the use of ascorbic acid up to 20% and that a pH of 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin. As such, it would have

been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the same would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that the Herstein teaches away from a stable solution, however, Applicant Herstein use the organoclay to stabilize an emulsion not a solution. Further, the stability of Applicant's invention requires pretreatment as disclosed in the Specification, which pretreatment is not set forth in claims 1,3-8, 10-16, 19 (Specification, pgs. 12, 16). Applicant cites to page 4, lines 24-25, however, there is no support for the argument that the present invention does not include an organoclay yet does not expand or lose integrity on storage. Applicant's Specification at pg. 6 indicates that expansion or integrity relate to creams with limited water content. Applicant acknowledges that the Specification discloses the use of amine salts. Applicant does not appear to explain the significance of this admission. It was Applicant who argued in a prior response that organoclays contain amine salts which would complex with ascorbic acid. Examiner notes that Applicant's own Specification discloses the use of organoclays (Paragraph 00062). Further, Applicant indicates that neutralized forms of ascorbic acid are within the scope of the invention, as such, Applicant has not shown how the possible complex of amine salts of organoclays with ascorbic acid overcomes the rejection.

Applicant argues that none of the prior art suggests having a pH of more than 3.5. The independent claims do not recite a pH of more than 3.5 but a range of 3.5 to 4.1. In any case, the prior art does teach a pH of 3.5-4.1. Herstein teaches that a pH within 3.5 to 4.1 is preferred to

facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 10, lines 6-17). Applicant argues that Murad teaches away from having a pH of more than 3.5 because Murad discloses oral administration, however, Applicant has provided no showing that pH is irrelevant to oral administration. Even in tablets and capsules, pH is a factor which must be accounted for; for example, see Schonmann et al. (US Pat. 4,894,978), Column 6, lines 48-55). Examiner cites to other oral dosage formulations in which pH is relevant to the formulation of the oral dosage form (See Green et al. (US Pat. 3,857,939), Column 1, lines 48-61 (pH of 4.3-5.2 for chewable ascorbic acid tablets); Ruff et al. (US Pat. 5,358,970), Column 1, lines 25-68, Column 2, lines 1-10 (Use of pH stabilizers in tablets and capsules to inhibit degradation of active ingredient). As such, Applicant's arguments do not show that pH is irrelevant to oral administration. Further, disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). The mere fact that the preferred embodiment is a capsule or tablet does not teach away from the broad disclosure which discloses as indicated above that ascorbic acid formulations include aqueous formulations. Thus, Applicant has not shown that Murad teaches away from the claimed invention.

With respect to Herstein, Applicant has provided no evidence that emulsions cannot have a pH. For example, see Woodward et al. (US Pat. 5,358,990), column 7, lines 50-55 (pH of emulsion was measured); Bissett (US Pat. 5,681,852), Column 8, lines 61-63 (disclosing preferred pH of emulsions). Applicant has not provided any evidence which refutes the disclosure of Herstein of 82% protonation or that organoclays which comprise amine salts complex with the ascorbic acid. The arguments of counsel cannot take the place of evidence in

the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). Further, Applicant's own Specification discloses the use of amine salts (Specification pgs. 8, 9).

With respect to Taylor, Taylor is no longer part of the rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1,3-8, 10-16, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594) and Darr et al. (US Pat. 5,140,043).

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which is applied once or twice daily (Column 2, lines 38-53, Column 4, lines 34-45, Claims 1, 2).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucoseamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or

suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught that zinc binds collagen fibers and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Darr et al. discloses that a pH of no more than about 3.5 ensures that greater than 82% of the ascorbic acid remins in the protonated, uncharged form and faciliates entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule (Column 3, lines 17-33, Column 4, lines 7-18, claims 1-42). Darr et al. discloses that at even at a pH of 4.5, a 5% solution of ascorbic acid remains quite stable and that at a pH of 4.2, 5% ascorbic acid remained stable (Column 5, lines 1-27).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, aminosugar, water and pH of 3.5 to 4.1. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and glucosamine, the use of ascorbic acid up to 20% and a pH of about 3.5 and that at pHs of 4.2 and 4.5, a 5% solution of ascorbic acid remained stable. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that a solution of ascorbic

acid at a pH of about 3.5 would be stable and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun.

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the same reasons as above to the extent the above is applicable. Further, with respect to Darr, Darr does not teach away from the claimed invention. The claimed invention includes a pH of 3.5. Applicant acknowledges that Darr discloses a pH of less than about 3.5 or no more than about 3.5. The claimed invention has a minimum pH of 3.5. Therefore, Darr discloses a pH falling within the scope of Applicant's claims. As indicated above, the rejection herein is based on a combination of references, as such, the fact that Schinitsky or Murad do not mention pH does not overcome the rejection. Taylor is not part of this rejection.

In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 191 USPQ 90 (CCPA 1976); In re Woodruff, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.); In re Geisler, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that suitable protection' is provided if the protective layer is about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range."). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges

do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
May 2, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600